

REMARKS

Reconsideration and withdrawal of the rejections of the pending claims are respectfully requested in view of the amendments and remarks herein, which place the application in condition for allowance.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1-8, 10-13 and 20-24 were pending in this application. Claims 1-8, 10-13 and 20-24 have been cancelled. Claims 25-44 have been added. Support for newly added claims 25-44 may be found in the claims as originally filed and, for example, in Figure 1 and on page 9 of the specification as originally filed. No new matter has been introduced.

The issues raised by the Examiner in the Office Action are addressed below in the order that they appear in the prior Action.

II. THE 35 U.S.C. § 103 REJECTIONS ARE OVERCOME

Applicants note that claims 1-8, 10-13 and 20-24 have been cancelled, thereby rendering their rejection moot. However, in the interest of expediting prosecution, Applicants point out that new claims 25-44 are patentable over the combinations of references that were cited in the Office Action for the reasons that follow.

Instant Claims are Patentable over Ko, Whittle, and Bechgaard.

Applicants assert that new claims 25-44 are patentable over Ko *et al.* (Journal of Microencapsulation 1998) ("Ko") in view of Whittle *et al.* (US 2002/0136752) ("Whittle") and further in view of Bechgaard *et al.* (US 5,397,771) ("Bechgaard").

Newly added independent claim 25 is directed to a "lipophilic formulation for nasal application, comprising: (a) at least one sexual hormone drug; (b) at least one lipophilic or partly lipophilic carrier comprising an oil; and (c) a compound or a mixture of compounds having surface tension decreasing activity, wherein the at least one sexual hormone drug is maintained at a serum level greater than baseline for at least six hours after a single application of the formulation."

Hence, the instant independent claim, and the claims depending therefrom, are distinguished over the cited references. For example, none of the cited references refers to a

lipophilic formulation wherein the at least one sexual hormone drug is maintained at a serum level greater than baseline for at least six hours after a single application of the formulation.

Instant Claims are Patentable over Ko, Whittle, Bechgaard, and Patel

Applicants assert that new claims 25-44 are patentable over Ko in view of Whittle and further in view of Bechgaard and Patel *et al.* (US 6,248,363) (“Patel”).

Applicants refer to the discussion above, which concluded that none of Ko, Whittle, or Bechgaard refers to a lipophilic formulation wherein the at least one sexual hormone drug is maintained at a serum level greater than baseline for at least six hours after a single application of the formulation. Further, Patel does not compensate for the deficiencies of Ko, Whittle, or Bechgaard.

Therefore, none of the instant claims are rendered obvious in view of the combination of Ko, Whittle, Bechgaard, and Patel.

Instant Claims are Patentable over Ko, Whittle, Bechgaard, and Lacy

Applicants assert that new claims 25-44 are patentable over Ko in view of Whittle and further in view of Bechgaard and Lacy *et al.* (US 5,645,856) (“Lacy”).

Applicants refer to the discussion above, which concluded that none of Ko, Whittle, or Bechgaard refers to a lipophilic formulation wherein the sexual hormone drug is maintained at a serum level greater than baseline for at least six hours after a single application of the formulation. Further, Lacy does not compensate for the deficiencies of Ko, Whittle, or Bechgaard.

Therefore, none of the instant claims are rendered obvious in view of the combination of Ko, Whittle, Bechgaard, and Lacy.

Instant Claims are Patentable over Illum, Ko, Patel, Dondeti, and Glass

In the interest of expediting prosecution, Applicants refer to the art rejections over Illum (US 5,863,554) (“Illum”), Ko, Patel, Dondeti *et al.* (International Journal of Pharmaceuticals 1996) (“Dondeti”), and Glass (US 5,897,894) (“Glass”) in the November 13, 2007 Office Action. Applicants refer to the discussion above, which concluded that Ko does not refer to a lipophilic formulation wherein the sexual hormone drug is maintained at a serum level greater than baseline for at least six hours after a single application of the formulation, and that Patel does not compensate for the deficiencies of Ko. Further, none of Illum, Dondeti or Glass compensate for the deficiencies of Ko.

Thus, none of the instant claims are rendered obvious in view of the combination of Illum, Ko, Patel, Dondeti and Glass.

III. THE DOUBLE PATENTING REJECTION IS OVERCOME

Claims 1-8, 10-12, 15, 18-19 and 21 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-8, 10-12, 16, 18-21 and 24-25 of copending Application No. 11/560,187.

While claims 1-8, 10-12, 15, 18-19 and 21 have been cancelled, rendering this rejection moot, Applicants point out that a Terminal Disclaimer was filed on October 14, 2008.

In view of the remarks and amendments herewith and those of record, the application is in condition for allowance. Favorable reconsideration of the rejections of the application and prompt issuance of a Notice of Allowance, or an interview at a very early date with a view to placing the application in condition for allowance, are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

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